Philips Medical Systems Nederland B.V.
Veenpluis 4-6, 5684-PC, Best
The Netherlands

PHILIPS

K062650

# 510(k) summary

The following information is submitted in accordance with the requirements of 21CFR 807.92.

SEP 21 2006

**Identification of manufacturer**

Company:..... Philips Medical Systems Nederland B.V.
Address:..... Veenpluis 4-6,
5684-PC, Best, The Netherlands
Registration number:..... 3003768277

**Identification of U.S. designated agent**

Company:..... Philips Medical Systems North America Company
Address:..... 22100 Bothell Everett Highway
Bothell, WA 98021-8431, U.S.A.
Registration number:..... 1217116

**Identification of official correspondent**

Name:..... Lynn Harmer
Position:..... Senior Manager, Regulatory Affairs
Telephone:.....(425) 487-7312
Date prepared:.....July 31, 2006

**Device identification**

Trade name:..... Philips
Device name:.....EP-Navigator
Regulation description:..... Picture archiving and communications system
Regulation number:.....21CFR 892.2050
Class:..... II
Product code:..... 90L--LZ

**Legally marketed devices**

Trade names:..... Brilliance CT, Private Practice CV configuration" CT scanner, Gemini PET/CT imaging system, Allura 3D-CA, Integris 3D-RA, Stentboost, Xper CT
Manufacturer:..... Philips (for all predicate devices)
510(k) numbers:..... K042293, K041955, K042334, K040254, K031836, K060749

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## Device description

Device description:.....EP-Navigator image processing algorithms are executed on a PC based hardware platform, which can perform the following functions:

- segment previously acquired DICOM 3D CT image data,
- superimpose the segmented 3D CT dataset on a live fluoroscopic X-ray image of the same anatomy, obtained on a Philips Allura Xper FD angiography X-ray system,
- register the segmented 3D CT data with live fluoroscopic X-ray images obtained on a Philips Allura Xper FD angiography X-ray sysem for specified procedures.

## Intended use

Intended use:.....EP-Navigator is intended to enable users to segment previously acquired 3D CT datasets and overlay and register these 3D segmented data sets with live fluoro X-ray images of the same anatomy in order to support catheter/device navigation during specified procedures.

## Technological characteristics

Conclusion:.....EP-Navigator is substantially equivalent to the currently legally marketed devices.

This opinion is based on the following:

- EP-Navigator does not introduce new indications for use,
- EP-Navigator has the same technological characteristics as the predicate devices,
- EP-Navigator does not introduce new potential hazards or safety risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 2 1 2006

Phillips Medical Systems
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, N.W.
BUFFALO MN 55313

Re: K062650
Trade/Device Name: EP-Navigator
Regulation Number: 21CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 5, 2006
Received: September 7, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K062650

Device Name: **EP-Navigator**

Indications for Use:

EP-Navigator is intended to enable users to segment previously acquired 3D CT datasets and overlay and register these 3D segmented data sets with live fluoro X-ray images of the same anatomy in order to support catheter/device navigation during specified procedures.

Prescription Use __yes_____ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use __No___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguram

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062650